

REMARKS

In the February 19, 2003 office action, the Examiner indicated that claims 1-53 were pending; claims 1-15, 40-43 and 48-53 were withdrawn from consideration; claims 16-33, 35-39, and 44-47 were allowed; and, claim 34 was rejected.

In this response, the Applicant has amended claims 16-18, 21-22, 26, 28-36, 38 and 44-47. New claims 54-130 have been added and claims 1-15, 40-43 and 48-53 remain withdrawn. Claims 16-39, 44-47 and 54-130 will be pending after entry of this response. Discussion and support for new claims 54-130, all of which incorporate the limitations of claim 16, are provided in a later section of this response.

No new matter has been introduced by the new or amended claims.

With respect to all amendments and cancelled claims, Applicant has not dedicated or abandoned any unclaimed subject matter and moreover has not acquiesced to any rejections and/or objections made by the Patent Office. Applicant reserves the right to pursue prosecution of any presently excluded claim embodiments in future continuation and/or divisional applications.

Interview

Applicant thanks the Examiner for extending the courtesy of a telephone interview with Applicant's representative, Dr. Madeline Johnston, on December 18, 2002.

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Response to Allowed Subject Matter

Claims 16-33, 35-39, and 44-47 have been indicated as allowed by the Examiner.

Applicant thanks the Examiner for allowance of these claims and presents herein amendments to the allowed claims as shown below.

Claim 16 has been amended to remove the formula designations (e.g. "Formula 3") and to remove the limitation "y * n is at least 3". It is noted that the species that was elected and searched by the Examiner, compound 25a in Figure 5, is in compliance with amended claim 16. To illustrate, compound 25a in Figure 5 may be described by Formula 4 in claim 16, with $n = 1$, $y = 2$ and $R^1 = G_2-(ONH_2)_n$. As the searched species did not inherently contain the limitation "y * n is at least 3", it is believed that removal of the phrase "y * n is at least 3" would not necessitate a new search to be conducted on the part of the Examiner. The Applicant respectfully requests allowance of amended claim 16.

Claim 17 has been amended to incorporate structural designations (e.g. straight chain, cyclic), to insert the term "independently" and to increase the range of carbon atoms to 1-5000. Support for these amendments may be found, e.g. on page 16, lines 4-20 of the specification as filed.

Claim 18 has been amended to correct a typographical style error.

Claim 21 has been amended to increase the range of oxyethylene units to 1-5,000. Support for this amendment may be found, e.g. on page 17, lines 16-19 of the specification as filed.

Claim 22 has been amended to correct a typographical spelling error.

Claim 26 has been amended to increase the range of oxyethylene units to 1-500. Support for this amendment may be found, e.g. on page 5, lines 27-31 of the specification as filed.

Claims 28-33 have been amended to remove the formula designations (e.g. "Formula 3").

Claim 35 has been amended to insert the term "independently".

Claim 36 has been amended to remove the formula designations, to insert semicolons, and to increase the range of n values to 1-5,000. Support for this amendment may be found, e.g. on page 16, lines 4-11 and page 17, line 4 (for CH_2)_n; and, on page 17, lines 16-19 (for $(\text{CH}_2\text{CH}_2\text{O})_n$) of the specification as filed.

Claim 38 has been amended to include a period at the end of the claim and to remove the formula designations (e.g. 125c).

Claim 39 has been amended to remove the formula designation.

Claims 44-47 have been amended to recite "one or more biologically active molecules" in reference to the claimed conjugates. While Applicant asserts that "a" means "one or more" in the context of these claims, the Applicant prefers to use the later terminology. This amendment is a non-narrowing, cosmetic amendment.

New Claims

There are no new independent claims introduced in this response. New dependent claims have been introduced and depend from claim 16. Support for the new dependent claims can be found throughout the specification as filed. The groupings below are for the convenience of the Examiner.

New Claims 54-58:

New claims 54-58 describe particular conjugates and are dependent on claims 44 or 45. Support for these claims can be found in the specification as filed, e.g. on page 2, lines 2-4 and

20-23; page 3, lines 3-5; page 7, lines 11-13; page 23, lines 25-28; and page 25, lines 23-37 *inter alia* (**claims 54**); *e.g.* on page 24, lines 13-25; page 30, Example 1; page 44, Example 10; and, Figure 1 (**claim 55**); *e.g.* on page 24, lines 21-25 (**claim 56**); *e.g.* page 29, lines 3-18 (**claim 57**); and, *e.g.* page 24, line 26 to page 25, line 12 (**claim 58**).

New Claims 59-88, 94:

Claims 59, 66, 73, 80-82 and 94 recite specific valency platform molecules and are dependent from claim 16. The dependent claims thereof, **claims 60-65, 67-72, 74-79 and 83-88** recite specific conjugates of the valency platform molecules claimed. Support for these claims may be found in the specification as filed, *e.g.* page 58, lines 11-20; Figure 28; page 30, Example 1; and, Figure 1 (**claims 59-65**); *e.g.* page 59, Example 22, lines 27-31; Figure 30, page 30, Example 1; and, Figure 1 (**claims 66-72**); *e.g.* page 60, Example 23, line 11 to page 61, line 8; Figure 31, page 30, Example 1; and, Figure 1 (**claims 73-79, 94**); *e.g.* page 7, line 1-14; page 15, line 4 to page 16, line 26; page 30, Example 1; and, Figure 1 (**claims 80-88**).

New Claims 89-93:

Claims 89-93 describe a method of making a conjugate according to claim 44, and are supported by the specification as filed, *e.g.* page 7, lines 15-23 and under the section located on page 23, entitled Conjugates, Methods of Preparation, and Uses Thereof.

New Claims 95-118, 120-125:

Claims 95 and 102 depend from claim 21 and further limit the number of oxyethylene units. Support for these claims may be found, *e.g.*, on page 17, lines 16-19 of the specification as

filed. **Claims 96-101** recite particular conjugates comprising a valency platform molecule of claim 21. Support for these claims may be found throughout the specification, *e.g.*, under the section located on page 23, entitled Conjugates, Methods of Preparation, and Uses Thereof.

Claims 103-105 depend from claim 16 and recite particular G_2 embodiments. Support for these claims may be found in the specification as filed, *e.g.* on page 5, lines 27-31 and page 19, lines 10-23.

Claims 106 -107 and 111 recite symmetry and valency embodiments of the valency platform molecules of claim 16. Support for these claims may be found, *e.g.* on page 13, lines 28-31 and page 21, lines 14-15.

Claims 108-110 are dependent from claim 16 and recite particular embodiments. Support for these claims may be found, *e.g.*, on page 21, line 25 to page 23, line 18.

Claim 112 is dependent from claim 17 and further limits the carbon atom ranges of R^c and G_2 . Support for this claim may be found, *e.g.* on page 16, lines 4-20.

Claims 113-118 and 120-123 recite particular conjugates. Support for these claims may be found throughout the specification, *e.g.*, under the section located on page 23, entitled Conjugates, Methods of Preparation, and Uses Thereof.

Claim 119 recites a pharmaceutical composition and is supported by the specification as filed, *e.g.* page 7, lines 24-25.

Claims 124 recites a composition comprising two or more valency platform molecules according to claim 29.

Claim 125 recites a particular embodiment of the valency platform molecule of claim 29.

Claims 126 -129 recite specific biologically active molecules, and are supported *e.g.*, on page 23, lines 25-31; page 24, lines 13-25; and, page 25, line 23 to page 26, line 16.

Claims 130 is dependent from claim 36, and recites the n value range to 1-500. Support for this amendment may be found, *e.g.*, on page 16, lines 4-11 and page 17, lines 16-19.

Applicant respectfully requests allowance of all pending claims.

Response to Rejections under 35 U.S.C. § 112, second paragraph

The Office has rejected claim 34 as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The Examiner states that none of the court citations mentioned in the previous response pertain to the use of the term “about” in reference to a range, and asserts that the issue is whether the upper limit to the polydispersity is 1.2, or some other number.

In response, the Applicant respectfully traverses the Examiner’s assertion that the term “about” is rendered indefinite when used to describe a range. Applicant submits that MPEP 2172.05(b), *Ex parte Eastwood*, 163 USPQ 316 (Bd. App. 1968), and *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540 (Fed. Cir. 1983) sanction the use of the term “about” as used in the instant claims. Both of these cases use the term about in conjunction with a range. *Ex parte Eastwood* concerned the use of the term ‘about’ to define the area range of the lower end of a mold as “between 25 to about 45%”. Similarly, *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, concerned the use the term ‘about’ in describing the stretch rate range of a plastic as “exceeding about 10% per second”. These cases refute the Examiner’s assertion that the term ‘about’ cannot be used in conjunction with a range.

A patentee has the right to claim the invention in terms understood by persons of skill in the art. (*Modine Mfg. Co. v. Int’l Trade Comm’n*, 75 F.3d 1545, 37 USPQ 2d 1609 (Fed. Cir. 1996); finding the term “about” to define a range of "about 0.015-0.040" to be definite, “Such broadening usages as ‘about’ must be given reasonable scope . . . although it is rarely feasible to

attach a precise limit to 'about,' the usage can usually be understood in light of the technology embodied in the invention.”). Applicant submits that the use of the clear, but flexible term “about” in claim 34 is not indefinite by law. Therefore, withdrawal of this ground for rejection is respectfully requested.

In addition, claim 34 has been amended with respect to the term “molecules” as suggested by the Examiner. The Applicant thanks the Examiner for his helpful claim language suggestion, which was used in amended claim 34. Support for this amendment may be found, *e.g.*, on page 13, lines 4-23. Applicant respectfully requests allowance of amended claim 34.

CONCLUSION

Applicants have, by way of the amendments and remarks presented herein addressed all issues that were raised in the outstanding Office Action. Applicant respectfully contends that this Amendment has overcome the rejections and that the pending claims are in condition for allowance. If it is determined that a telephone conversation would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the unlikely event that the transmittal letter is separated from this document and the Patent Office determines that an extension and/or other relief is required, Applicant(s) petition(s) for any required relief including extensions of time and authorizes the Assistant Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket no. 252312007300.

Respectfully submitted,

Dated: _____, 2003

By: _____

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